SAFETY DATA SHEET

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Azithromycin dihydrate capsules

Product Code(s) 234
Trade Name: ZITHROMAX; AZENIL; AZITROCIN; ZETAMAX; ZITROMAX; ZITHROMAC
Chemical Family: Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used as antibiotic agent

1.3. Details of the supplier of the safety data sheet

Pfizer Inc
66 Hudson Boulevard East
New York, New York 10001
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Hazardous to the aquatic environment - acute Category 1 - (H400)
Hazardous to the aquatic environment - chronic Category 1 - (H410)

OSHA Classification

Hazards not otherwise classified (HNOC)
Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200
Not applicable

2.2. Label elements

Signal word Warning

Hazard statements H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements - EU (§28, 1272/2008) P273 - Avoid release to the environment
P391 - Collect spillage
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

PBT & vPvB The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Azithromycin dihydrate (CAS #: 117772-70-0)	50 - 55		Not Listed	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Not classified	100	10
Sodium lauryl sulfate (CAS #: 151-21-3)	< 1		205-788-1	Acute Tox.4 (H302) Skin Irrit.2 (H315) Eye Dam.1 (H318) Aquatic Chronic 3 (H412)	10-<20% Eye Irrit 2 >=20% Eye Dam 1	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No.	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)

				1272/2008 [CLP]			
Lactose (CAS #: 63-42-3)	*	-	200-559-2	Not classified	Not classified	No data available	No data available
Starch (CAS #: 9005-25-8)	*	-	232-679-6	Not classified	Not classified	No data available	No data available
Magnesium Stearate (CAS #: 557-04-0)	*	-	209-150-3	Not classified	Not classified	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Azithromycin dihydrate 117772-70-0	> 2000	No data available	No data available	No data available	No data available
Lactose 63-42-3	10000	No data available	No data available	No data available	No data available
Magnesium Stearate 557-04-0	> 2000	No data available	>2	No data available	No data available
Sodium lauryl sulfate 151-21-3	1200	>2000	0.975	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information
* Proprietary
Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation Remove to fresh air. Seek immediate medical attention/advice.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Skin contact Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

Explosion data
Sensitivity to mechanical impact No information available.
Sensitivity to static discharge No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.
Methods for cleaning up Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated surface thoroughly.
Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken,. avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly

after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

Azithromycin dihydrate

Pfizer OEL TWA-8 Hr: 500 µg/m³

Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr: 300 µg/m³

Starch

ACGIH TLV	TWA: 10 mg/m³
Bulgaria	TWA: 10.0 mg/m³; dust, inhalable fraction
Czech Republic	4.0 mg/m³
Ireland	TWA: 10 mg/m³; total inhalable dust TWA: 4 mg/m³; respirable dust STEL: 30 mg/m³ (calculated); respirable dust STEL: 12 mg/m³ (calculated);
Russia	MAC: 10 mg/m³
Spain	TWA-(VLA-ED): 10 mg/m³;
Switzerland	TWA-MAK: 3 mg/m³; respirable dust
OSHA PEL	TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction
United Kingdom	TWA: 10 mg/m³; total inhalable TWA: 4 mg/m³; respirable STEL: 30 mg/m³; total inhalable STEL: 12 mg/m³; respirable

Magnesium Stearate

ACGIH TLV	TWA: 10 mg/m³ inhalable particulate matter TWA: 3 mg/m³ respirable particulate matter TWA: 10 mg/m³ inhalable particulate matter except stearates of toxic metals TWA: 3 mg/m³ respirable particulate matter except stearates of toxic metals
Ireland	TWA: 10 mg/m³; STEL: 30 mg/m³ (calculated;except Lead stearate);
Spain	TWA-(VLA-ED): 10 mg/m³;

8.2. Exposure controls

Engineering controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal protective equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Eye/face protection	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).
Hand protection	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).
Skin and body protection	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
Respiratory protection	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).
Thermal hazards	No information available.
Environmental exposure controls	No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Capsule
Physical state	Solid
Color	Red
Odor	No information available.
Odor threshold	No information available

Property	**Values**
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	

SADT (°C)	No data available
pH	No data available
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)
Azithromycin dihydrate
Measured 7 Log P 0.67
Sodium lauryl sulfate
Measured Log P 0.83

9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

9.2.1. Information with regard to physical hazard classes
No information available

9.2.2. Other safety characteristics
No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity
Reactivity No information available.
10.2. Chemical stability
Stability Stable under normal conditions.
Explosion data
Sensitivity to mechanical impact No information available.
Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions
Possibility of hazardous reactions No information available.

Hazardous polymerization Will not occur.
10.4. Conditions to avoid
Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.
10.5. Incompatible materials
Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products
Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information: The information included in this section describes the potential hazards of the individual ingredients

Short term May cause irritation (based on animal data) Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: diarrhea, nausea, abdominal pain, irregular heartbeat (cardiac arrhythmia), liver effects, allergic reaction.

Acute toxicity Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation Based on available data, the classification criteria are not met.
Skin corrosion/irritation Based on available data, the classification criteria are not met.
Respiratory or skin sensitization Based on available data, the classification criteria are not met.
STOT - single exposure Based on available data, the classification criteria are not met.
STOT - repeated exposure Based on available data, the classification criteria are not met.
Reproductive toxicity Based on available data, the classification criteria are not met.
Germ cell mutagenicity Based on available data, the classification criteria are not met.
Carcinogenicity Based on available data, the classification criteria are not met.
Aspiration hazard Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)
Azithromycin dihydrate
Mouse (F) Oral LD50 4000 mg/kg
Mouse (M) Oral LD50 3000 mg/kg
Rat Oral LD50 > 2000 mg/kg
Magnesium Stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3
Sodium lauryl sulfate
Rat Oral LD50 1200 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Lactose	> 10 g/kg (Rat)	-	-
Magnesium Stearate	> 10000 mg/kg (Rat)	-	-
Sodium lauryl sulfate	= 1288 mg/kg (Rat)	= 200 mg/kg (Rabbit)	> 3900 mg/m^3 (Rat) 1 h

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)
Azithromycin dihydrate
Antigenicity- Active anaphylaxis Guinea Pig Negative
Antigenicity- Passive cutaneous anaphylaxis Rabbit Negative
Antigenicity- Passive cutaneous anaphylaxis Mouse Negative
Sodium lauryl sulfate
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild Moderate
Skin Sensitization - GPMT Guinea Pig Negative
Skin Sensitization - LLNA Mouse Negative
Irritation / Sensitization Comments: Azithromycin may be slightly irritating to eyes, based on extrapolation of minimal and moderate irritation seen in intravenous and intramuscular irritation studies, respectively.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Azithromycin dihydrate
1 Month(s) Rat Oral 50 mg/kg/day LOAEL Liver
1 Month(s) Dog Oral 25 mg/kg/day LOAEL Liver
6 Month(s) Rat Oral 40 mg/kg/day LOAEL Liver
6 Month(s) Dog Oral 10 mg/kg/day LOAEL Liver
1 Month(s) Rat Intravenous 5 mg/kg/day NOAEL Liver
1 Month(s) Dog Intravenous 5 mg/kg/day NOAEL Liver
Magnesium Stearate
13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Azithromycin dihydrate
Reproductive & Fertility Rat Oral 10 mg/kg/day NOEL Fertility
Peri-/Postnatal Development Rat Oral 40 mg/kg/day NOEL Not Teratogenic
Embryo / Fetal Development Mouse Oral 200 mg/kg/day NOAEL Fetotoxicity, Maternal Toxicity
Embryo / Fetal Development Rat Oral 40 mg/kg/day NOAEL Fetotoxicity, Maternal Toxicity
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day LOAEL Maternal Toxicity
Embryo / Fetal Development Rabbit Oral 40 mg/kg/day NOAEL Fetotoxicity, Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
Azithromycin dihydrate
Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Cytogenetics Mouse Lymphoma Negative
In Vitro Cytogenetics Mouse Negative
In Vitro Cytogenetics Human Lymphocytes Negative
Sodium lauryl sulfate
Bacterial Mutagenicity (Ames) *Salmonella* Negative

Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

11.2. Information on other hazards
11.2.1. Endocrine disrupting properties
Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information
Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. In the environment, this substance is expected to. mainly reside in the aquatic environment and slowly degrade. Classification based on data available for ingredients.

12.1. Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)
Azithromycin dihydrate
Daphnia magna (Water Flea) OECD EC50 48 hours 120 mg/L
Hyallela azteca (Freshwater Amphipod) OECD LC50 96 hours > 120 mg/L
Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 hours > 84 mg/L
Green Algae OECD EC50 72 Hours 0.0037 mg/L
Microcystis aeruginosa (Blue-green Alga) OECD ErC50 96 hours 0.0018 mg/L
Sodium lauryl sulfate
Cyprinodon variegatus (Sheepshead Minnow) LC50 96 hours 4.1 mg/L

Ceriodaphnia dubia (Daphnids) EC50 48 hours 5.55 mg/L
Desmodesmus subcapitata (Green Alga) ErC50 72 hours > 120 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Azithromycin dihydrate

Aspergillus niger (Fungus) OECD MIC > 1000 mg/L
Trichoderma viride (Fungus) OECD MIC > 1000 mg/L
Clostridium perfingens (Bacterium) OECD MIC 2.0 mg/L
Bacillus subtilis (Bacterium) OECD MIC 2.0 mg/L

Terrestrial Toxicity: (Species, Method, End Point, Duration, Result)

Azithromycin dihydrate

Eisenia foetida (Earthworm) TAD NOEC 28 Days 1000 mg/kg

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Azithromycin dihydrate

Pimephales promelas (Fathead Minnow) OECD 32 Day(s) NOEC 4.6 mg/L Survival
Ceriodaphnia dubia (Daphnids) OPPTS 7 Day(s) NOEC 0.0044 mg/L Reproduction

Sodium lauryl sulfate

Pimephales promelas (Fathead Minnow) 42 Day(s) NOEC => 1.357 mg/L Survival Growth
Ceriodaphnia dubia (Daphnids) 7 Day(s) NOEC 0.88 mg/L Reproduction

12.2. Persistence and degradability

Persistence and degradability No information available.

Sodium lauryl sulfate

OECD Activated sludge Ready 94-97 % After 28 Day(s) Ready

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

Azithromycin dihydrate

Measured 7 Log P 0.67

Sodium lauryl sulfate

Measured Log P 0.83

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Sodium lauryl sulfate	Not PBT/vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.
PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products
Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number: UN 3077
UN proper shipping name: Environmentally Hazardous Substance, Solid, n.o.s (Azithromycin dihydrate)
Transport hazard class(es): 9
Packing group: III
Environmental Hazard(s): Marine Pollutant

5 kg/5L Exception:
UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not subject to the dangerous goods transportation regulations by any mode:

* Single packagings containing a net quantity of 5 liters or less for liquids or a net mass of 5 kg or less for solids.
* Combination packagings containing a net quantity per inner packaging of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Azithromycin dihydrate
CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
EINECS Not Listed

Lactose
CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
TSCA Present
EINECS 200-559-2
AICS Present

Starch
CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed

TSCA	Present
EINECS	232-679-6
AICS	Present

Magnesium Stearate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	209-150-3
AICS	Present

Sodium lauryl sulfate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	205-788-1
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 6

National regulations

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)
Not applicable

TRGS 905 Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018	Not applicable
Storage of Hazardous Material	Not applicable
WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20	Not applicable
Major Accidents Ordinance SR 814.012	Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:
This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants
Not applicable

Ozone-depleting substances (ODS) Regulation (EU) 2024/590
Not applicable.

Explosives Precursors Marketing and Use (2019/1148)
Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing Chemicals Inventory
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15
H302 - Harmful if swallowed. H318 - Causes serious eye damage. H315 - Causes skin irritation. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects. H401 - Toxic to aquatic life. H412 - Harmful to aquatic life with long lasting effects.

Data Sources:	Pfizer proprietary drug development information. Safety data sheets for individual ingredients.
Reason for revision	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 14 - Transport Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.
Revision date	14-Jun-2025
Prepared By	Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.